BOARDS AND COMMISSIONS

Kentucky Board of Veterinary Examiners

(Amended After Comments)

201 KAR 16:552. Responsibilities for certified animal control agencies; limitations on drugs.

RELATES TO: KRS 321.181, 321.207, 321.235 [~~321.235(7)~~], 321.351

STATUTORY AUTHORITY: KRS 321.207(1) – (3),(5)-(8), 321.235(1)(a), (b), (2)(b)3. [~~(1), (2), 321.235(3), 321.240(5)~~]

NECESSITY, FUNCTION, AND CONFORMITY: KRS 321.207(1) permits the Kentucky Board of Veterinary Examiners to authorize an animal control agency to apply for a registration certificate by the United States Drug Enforcement Administration (DEA) to **procure, manage, and dispose of**[~~**order, purchase, manage, and store**~~]controlled substances which are authorized by the board for use in animal sedation and euthanasia. KRS 321.207(2) requires the applicant agency to comply with administrative regulations that establish standards for the proper storage and handling of the drugs the board has authorized for use, and other provisions that may be necessary to ensure that the drugs are used safely and solely for the purpose of euthanizing animals. KRS 321.235(1)(a), (b), (2)(b)3. authorizes [~~KRS 321.235(3) and 321.240(5) authorize~~] the board to promulgate administrative regulations to implement KRS Chapter 321. This administrative regulation establishes the duties for the animal control agency designated on-site manager, standards for proper drug storage, and drugs that may be used by certified animal control agencies and the certified animal euthanasia specialists they employ.

Section 1. **Definitions.**

(1) "Dispose" in relation to drugs means to destroy or transfer.

(2) "Manage" in relation to drugs means to administer, dispense, or inventory.

(3) "Procure" in relation to drugs means to order, purchase, or receive.

Section 2. Responsibilities of a Certified Animal Control Agency. **A certified animal control agency shall:**

(1) **Ensure [~~A certified animal control agency and~~]** staff shall comply with all requirements of KRS Chapter 321 and 201 KAR Chapter 16.

(2) **Identify[~~A certified animal control agency shall identify~~]** an agency designated on-site manager and ensure the person complies with the requirements in Section 2 of this administrative regulation.

(3) **Report any[~~Any~~]** change to the designated on-site manager **[~~shall be reported~~]**in writing to the board within ten (10) business days by submitting a completed Request for a New Designated On-site Manager form or online equivalent form, including all required attachments.

(4) **Notify the board in writing within ten (10) business days following the termination or severance of employment of a certified animal euthanasia specialist in order that the certificate of the animal euthanasia specialist may be moved to inactive status.**

(5) Ensure[~~A certified animal control agency shall ensure~~] that the United States Drug Enforcement Administration (DEA) Controlled Substances Registration is kept in active status if there are controlled substances in the possession of the animal control agency.

(6)[~~(5)~~] Submit[~~A certified animal control agency shall submit~~] to inspection by a board representative at any time, with or without advanced notice in accordance with 201 KAR 16:550, Section 5.

(7) Report to the board and to DEA within twenty-four (24) hours any suspected diversion of controlled substances or theft of controlled substances.

Section 3[~~**Section 2**~~]. Responsibilities of a Designated On-site Manager.

(1) The designated on-site manager shall be responsible for reviewing educational materials provided by the board and submitting a responsive answer sheet for review by the board. A board inspector or representative shall periodically review educational materials with the designated on-site manager.

(2) The designated on-site manager shall:

(a) Ensure proper controls are in place in accordance with all state and federal laws for all controlled substances and other drugs at the animal control agency;

(b) Ensure drugs for euthanasia and drugs used for sedation prior to euthanasia shall be limited to the substances identified in Section 3 of this administrative regulation;

(c) Ensure all employees authorized to conduct animal euthanasia at the certified animal control agency are trained and certified in accordance with the requirements of 201 KAR 16:560 and 16:562, unless the employee is a board-licensed veterinarian or board-licensed veterinary technician;

(d) Ensure all animal euthanasia specialists who conduct euthanasia at the certified animal control agency maintain an active certificate with the board;

(e) Notify the board in writing within ten (10) business days following the termination of a certified animal euthanasia specialist so the certificate of the animal euthanasia specialist may be taken out of "active" status;

(f) **Develop** [~~**Shall develop**~~] and maintain standard operating procedures in writing for carcass disposal in accordance with all state and local laws and ordinances; [~~**and**~~]

(g) **Ensure that a designated area is provided for animal euthanasia activities, and that the area is kept clean and orderly, and is maintained as a safe workspace;**

(h) Ensure that drugs ordered under DEA Registration held by any person or entity other than the certified animal control agency are kept in separate secure storage pursuant to KRS 321.207(8); and

(i) Be [~~Shall be~~] responsive and cooperative to the board's request for access and information to the certified animal control agency.

(3) The designated on-site manager shall ensure that the animal euthanasia process shall be conducted within the restrictions set forth in this subsection.

(a) Euthanasia shall only be conducted upon animals owned by the certified animal control agency, except in cases of emergency care as defined by KRS 321.181(33) [~~KRS 321.181(10)~~].

1. Transfer of ownership or a temporary contract shall not be used for the purpose of circumventing this subsection; and

2. Wildlife shall be redirected to one (1) of the following:

a. A [~~a~~] board-licensed veterinarian;[~~,~~]

b. A Certified Wildlife Rehabilitator authorized to operate pursuant to 301 KAR 2:075;[~~, or~~],

c. A [~~a~~] Commercial Nuisance Wildlife Control Operator authorized to operate pursuant to 301 KAR 3:120;

d. A Captive Wildlife Holder authorized to operate pursuant to 301 KAR 2:081; **[~~or~~]**

e. A Wildlife Transporter authorized to operate pursuant to 301 KAR 2:082;

f. KDFWR wildlife biologist; or

g. KDFWR conservation officer.

(b) Euthanasia shall only be conducted upon the premises of the certified animal control agency, except in cases of emergency care as defined by KRS 321.181(33) [~~KRS 321.181(10)~~]; and

(c) All euthanized animals shall be disposed of in accordance with the certified animal control agency's standard operating procedures for carcass disposal.

Section 4[~~**Section 3**~~]. **Authorized**[~~**Approved**~~] Drugs for Animal Euthanasia and Anesthesia or Sedation of Animals Prior to Euthanasia.

(1) A certified animal control agency shall be restricted to the purchase of only **sodium pentobarbital** [~~**the following board-approved specific drugs**~~] for the purpose of animal euthanasia. [~~The drugs approved by the board for euthanasia are:~~]

[~~**(a) Sodium pentobarbital; and**~~

~~**(b) Sodium pentobarbital with lidocaine.**~~]

(2) A certified animal control agency shall be restricted to the purchase of only the following **board-authorized** [~~**board-approved**~~] specific drugs, or any combination thereof, for the purpose of animal anesthesia or sedation prior to euthanasia. [~~The drugs approved by the board for animal anesthesia or sedation prior to euthanasia are, or any combination thereof:~~]

(a) Acepromazine;

(b) Dexmedetomidine;

(c) Ketamine [~~(30 day supply or less)~~]; and

(d) Xylazine.

(3) Scheduled drugs (controlled substances) shall be limited to a thirty (30) day supply, **or the smallest quantity available for purchase if that quantity is greater than a thirty (30) day supply**.

(4) DEA's Schedule II order forms (titled "DEA-222") shall be used for each purchase or transfer of board **authorized** [~~approved~~]controlled substances.

(5)[~~(4)~~] Expired drugs.

(a) Expired drugs shall not be used.

(b) Expired drugs shall be properly disposed of in accordance with Section 7 of this administrative regulation.

Section 5[~~**Section 4**~~]. Storage.

(1) Board **authorized** [~~**approved**~~]euthanasia and sedation drugs shall be stored at the DEA address of record for the certified animal control agency in a **secure steel safe or** securely locked **steel** cabinet within:

(a) A [~~a~~] locked storage room;[~~,~~] or

(b) Other locked [~~other~~] enclosure; and [~~at the DEA address of record for the certified animal control agency.~~]

(c) **If the cabinet weighs less than 750 lbs, the**[~~**The**~~] cabinet shall be bolted securely to the floor or wall.

(2) DEA Controlled Substance Schedule II order forms shall be maintained at the DEA address of record for the certified animal control agency [~~stored~~] in a securely locked cabinet that is: [~~,~~]

(a) Separate [~~separate~~] from the storage location of the drugs;[~~,~~]

(b) Within [~~within~~] a locked storage room; or

(c) Other locked [other] enclosure [~~at the DEA address of record for the certified animal control agency~~].

Section 6[~~**Section 5**~~].

Disposal of Needles and Medical Waste.

(1) All needles in an animal control agency shall:

(a) Not be accessible to the public;

(b) After one (1) use, be rendered incapable of re-use [~~use~~]; and

(c) Be disposed of in an approved biohazard or sharps container.

(2) All syringes used in the process of euthanasia shall be disposed of in an approved biohazard or sharps container.

Section 7[~~**Section 6**~~]. Records.

(1) A certified animal control agency shall maintain records of **procurement, management, and disposal** [~~**purchases, administration**~~] of **board authorized**[~~**board approved**~~] euthanasia drugs and sedation drugs **as listed in Section 3 of this administrative regulation** [~~**, transfer, and destruction of drugs**~~] for a minimum of two (2) years.

(2) Records of administration shall include, at a minimum, the following [~~information~~]:

(a) The date of use;

(b) Identification of the animal;

(c) The amount of the drug used;

(d) Any amount wasted;

(e) The signature of the person administering the drug;

(f) The signature of the designated on-site manager certifying the accuracy of the administration of board **authorized**[~~**approved**~~] euthanasia drugs and sedation drugs not less than once per month; and

(g) The signature of the designated on-site manager certifying to the accuracy of the records not less than once per month, as well as on the annual inventory.

(3) Records of **procurement**[~~**purchase**~~] and destruction of board **authorized**[~~**approved**~~] euthanasia drugs and sedation drugs shall be maintained in a separate file from the records of administration of those substances.

(4) The records of **procurement, management, and disposal** [~~**purchase, destruction, and administration**~~] may be audited by representatives of the DEA or authorized designees of the board to determine adequacy, accuracy, and validity of the recordkeeping. The board may impose restrictions and administrative penalties on certificate holders or designated on-site managers as a result of substandard controls or records of the drugs.

(5) The records of purchase, administration, transfer, and destruction of euthanasia and sedation drugs, shall be maintained at the DEA address of record for the certified animal control agency.

Section 8[~~**Section 7**~~]. Destruction or Disposal of Drugs. Drugs at an animal control agency that require disposal shall be disposed of in accordance with one (1) of the methods set forth in this section. A written receipt with appropriate signatures shall be obtained for the methods in subsections (1) through (3) of this section, and a record of the action taken shall be made for the method in subsection (4) of this section. The record shall be maintained with the drug logs at the animal control agency.

(1) Transfer non-expired, non-controlled drugs to a licensed veterinarian.

(2) Transfer non-expired, controlled drugs to a DEA registered, board-licensed veterinarian using DEA Form 222. Copies of the DEA Form 222 shall be distributed per federal law.

(3) Surrender expired or non-expired drugs to local law enforcement for destruction.

(4) Inject expired or non-expired drugs into and incinerate an animal carcass in accordance with state and local rules on incineration. Written documentation shall describe the amounts disposed of, type of carcass, date of injection and incineration, witnesses, and any other pertinent details.

Section 9[~~**Section 8**~~]. Disciplinary Action. An animal control agency, designated on-site manager, and [~~credentialed~~] animal euthanasia specialists shall be subject to disciplinary action pursuant to KRS 321.235 and 321.351 for a violation of state or federal statutes or administrative regulations.

Section 10[~~**Section 9**~~].

Incorporation by Reference.

(1) "Request for a New Designated On-site Manager", 07/2023[~~12/2022~~], is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subjected to applicable copyright law, at the Kentucky Board of Veterinary Examiners, 107 Corporate Drive, Frankfort, Kentucky 40601, Monday through Friday, 8:30 a.m. to 4:30 p.m. This material may also be obtained at www.kybve.com.

11/13/2023

p.p Michelle M. Shane, Executive Director
on behalf of John C. Park, DVM, Board Chair
Kentucky Board of Veterinary Examiners

Date

201 KAR 16:552

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Michelle Shane, Executive Director
Phone: 502-782-0273
Email: Michelle.Shane@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes, for Board-certified animal control agencies, the standards for proper drug storage, limitations on the drugs that may be used by the agencies and the certified animal euthanasia specialists they employ, limitations on the animals on which the drugs may be used so that the specialists do not practice veterinary medicine outside the scope allowable by the General Assembly. In addition, this regulation outlines the responsibilities of the agency's Designated On-site Manager, who is in charge of controlled substances, including drug storage requirements, record keeping requirements, and limitations on options for the methods used for the destruction of drugs and sharps.

(b) The necessity of this administrative regulation:

As mandated by the General Assembly in KRS 321.207, this administrative regulation is necessary to establish the drugs that may be used by certified animal control agencies and the certified animal euthanasia specialists they employ, and standards for proper drug storage and handling.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

KRS 321.207 specifically requires the board to promulgate administrative regulations for board-certified animal control agencies limiting the type of drugs allowable for use by certified animal control agencies and the certified animal euthanasia specialists they employ, and establishing standards for proper drug storage and handling.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This administrative regulation will assist in effective administration by clearly detailing limitations on the operations of certified animal control agencies so that they do not exceed their operating scope as authorized by the General Assembly.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

Updating statutory references to conform with the new Kentucky Veterinary Medicine Practice Act, KRS Chapter 312; adding additional options for the redirection of wildlife; adding limitations on the office stock for all controlled substances; and formatting the requirements so they are easier for constituents to understand.

(b) The necessity of the amendment to this administrative regulation:

Changes are necessary to conform with the new Kentucky Veterinary Medicine Practice Act, KRS Chapter 312. The Kentucky Board of Veterinary Examiners has determined this amendment is necessary to place strict limits on the supply of controlled substances in a certified animal control agency, and provide additional options to redirect wildlife.

(c) How the amendment conforms to the content of the authorizing statutes:

KRS 321.207 specifically requires the board to promulgate administrative regulations related to board-certified animal control agencies, including requirements for storage and limitations on drugs.

(d) How the amendment will assist in the effective administration of the statutes:

This amendment shall ensure transparency about the requirements for allowable drugs, as well as their storage, maintenance, and use.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

50 board-certified animal control agencies and 232 animal euthanasia specialists, and future applicants.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

All board-certified animal control agencies shall be required to ensure adequate locked and secure storage for the management of controlled substances onsite, and limit their supply of controlled drugs to those listed by board in this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

Board-certified animal control agencies should already be properly ordering, storing,

and managing controlled drugs as a part of requirements established by the Drug Enforcement Administration (DEA), so there should not be any additional costs.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

By complying with this administrative regulation, entities should reduce break-ins and thefts of controlled substances, as well as be able to more easily comply with DEA Requirements related to drug record keeping. Animal Control Agencies should also reduce their liability to the public by limiting their scope of practice for board-certified euthanasia specialists, ensuring sharps are properly disposed of, and ensuring proper carcass disposal in compliance with local laws.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No costs are anticipated.

(b) On a continuing basis: No costs are anticipated.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

This administrative regulation does not establish fees. Funding for the KBVE comes from licensure and certification fees.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

There is no anticipation of an increase in fees or needed funding to implement this administrative regulation, as the KBVE is already running an administrative program to process applications and an inspection program to ensure compliance.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

No fees are established or increased by this administrative regulation.

(9) TIERING: Is tiering applied? (Explain why or why not)

No. All regulated entities have the same requirements.

201 KAR 16:552

FISCAL NOTE

Contact Person: Michelle Shane, Executive Director
Phone: 502-782-0273
Email: Michelle.Shane@ky.gov

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

The Kentucky Board of Veterinary Examiners and board-certified animal control agencies.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 321.207(1) – (3),(5)-(8), 321.235(1)(a), (b), (2)(b)3.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

No revenue will be generated from this filing. An animal control agency may need to expend monies to ensure adequate storage for controlled substances management.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

No revenue will be generated from this filing.

(c) How much will it cost to administer this program for the first year?

This is not a new program. Staff time will be required for record keeping.

(d) How much will it cost to administer this program for subsequent years?

Staff time will be required for record keeping. Costs will be very minimal.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): None.

Expenditures (+/-): None or negligible.

Other Explanation: n/a

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

There will be no cost savings; this administrative regulation simply codifies the requirements of drug management and establishes limitations on drug administration, making them easily accessible for regulated entities.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

There will be no cost savings.

(c) How much will it cost the regulated entities for the first year?

An animal control agency may need to expend monies to ensure adequate storage for controlled substances management. There will be no additional costs involved.

(d) How much will it cost the regulated entities for subsequent years?

There will be no additional costs involved.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-): None.

Expenditures (+/-): None or negligible.

Other Explanation: n/a

(5) Explain whether this administrative regulation will have a major economic impact, as defined below. *"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)]*

This amendment shall not have a "major economic impact", as defined in KRS 13A.010(13).

STATEMENT OF CONSIDERATION
Relating to 201 KAR 16:552

Kentucky Board of Veterinary Examiners
(Amended After Comments)

I. The public hearing on 201 KAR 16:550, 201 KAR 16:552, 201 KAR 16:560, 201 KAR 16:701, 201 KAR 16:702, and 201 KAR 16:750 scheduled for September 25, 2023, at 1:00 p.m. at the Office of the State Veterinarian, 107 Corporate Drive, Frankfort, KY 40601, was held, and written comments were received during the public comment period.

II. The following people either attended the hearing, submitted written comments, or both:

Name and Title	Agency / Organization / Entity / Other
O. Wayne Bailey, DVM	Countryside Animal Hospital (Mt. Sterling, KY)
James Beckman, DVM	Gas Light Equine (Westport, KY)
Abbey E. Biddle, DVM	Commonwealth Veterinary Clinic (Georgetown, KY)
William E. Bollinger, DVM	Central Kentucky Veterinary Center (Georgetown, KY)
Ashley Book, Director	Louisville Metro Animal Services (Louisville, KY)
Emily P. Bridge, DVM	Commonwealth Veterinary Clinic (Georgetown, KY)
Mark Brengelman, Attorney and Legal Counsel for the Board	Kentucky Board of Veterinary Examiners (KBVE) (Frankfort, KY)
Amanda C. Briggs	KBVE Board Staff (Frankfort, KY)
Jason A. Burcham, DVM	Tri Point Veterinary Clinic (Hebron, KY)
Irene Carter-Ballard, DVM	Town & Country Veterinary Services (Lebanon, KY)
Johanna Choate, DVM	Choate Veterinary Services (Almo, KY)
Darrell L. Coffey, DVM	Russell County Animal Clinic (Russell Springs, KY)
Janet D. Donlin, DVM, on behalf of AVMA	American Veterinary Medical Association (AVMA) (national)
Catherine Donworth, MVE	Donworth Veterinary (Lexington, KY)
LaNita S. Flanary, DVM	Flanary Veterinary Clinic (Paducah, KY)
Tim R. Gardner, DVM	KBVE Board Member (Scottsville, KY)
Brandy Glaza, Hospital Manager	Licking Valley Veterinary Services (Butler, KY)
Nathan Glaza, DVM	Licking Valley Veterinary Services (Butler, KY)
Linda K. Grimes, DVM	Animal Clinic of Estill County (Irvine, KY), and Animal Control Advisory Board (ACAB) (statewide)
Debra Hamelback, Executive Director on behalf of Members of the KVMA Board	Kentucky Veterinary Medical Association (KVMA) (statewide)

Robert B. "Chip" Harkins, LVT, and on behalf of KVTA	Crescent Hill Animal Hospital (Louisville, KY) and Kentucky Veterinary Technician Association (KVTA) (statewide)
Robert E. Holland, Jr., DVM, PhD.	Robert E Holland Jr DVM PSC (Lexington, KY)
John A. Keith, DVM, MBA, MEcon	Crossroads Veterinary Clinic, LLC (Versailles, KY)
Amy Kerley, DVM	Progressive Animal Healthcare (Paducah, KY)
W. Wade King, DVM	Frankfort Animal Clinic (Frankfort, KY)
Barb Lewis, MA, LVT, VTS (Clinical Pathology)	Morehead State University (Morehead, KY)
Mike McNutt, AES, and on behalf of KACCA	Hardin County Animal Control (Elizabethtown, KY), and Kentucky Animal Care and Control Association (KACCA) (statewide)
Barbie M. Papajeski, MS, LVT, RLATG, VTS (Clinical Pathology)	Hutson School of Agriculture (Murray, KY)
John C. Park, DVM	KBVE Chairman (Lexington, KY)
Denia M. Pelphrey, DVM	Corydon Animal Hospital, Inc. (Corydon, IN)
Stephanie W. Raispis, DVM	Wilderness Trace Vet Clinic (Junction City, KY)
Andre Regard, Attorney	Regard Law Group (Lexington, KY)
R. Thomas Riney, DVM	Nicholasville Road Animal Hospital (Lexington, KY)
Jason L. Rodgers, DVM	Lone Oak Animal Clinic (Paducah, KY)
Phillip E. Russo, CAE on behalf of NAVTA	National Association of Veterinary Technicians in America (NAVTA) (national)
Michelle Shane, Executive Director	KBVE Board Staff (Frankfort, KY)
Debra K. Shoulders, DVM	House Calls for Paws & Claws (Bowling Green, KY)
Tammy T. Smith, DVM	Knox County Veterinary Services (Barbourville, KY)
Scott A. Steele, MS, LVT, VTS (Dentistry), and on behalf of KVTA and NAVTA	Clays Mill Veterinary Clinic (Lexington, KY), and Kentucky Veterinary Technician Association (KVTA) (statewide), and National Association of Veterinary Technicians in America (NAVTA) (national)
Aaron H. Stamper, DVM	Pet WOW (Highland Heights, KY)
Rachael Stephenson, LVT	Progressive Animal Healthcare (Paducah, KY)
Angalyn D. Theno, DVM	Bluegrass Animal Care Center (Radcliff, KY)
Jon M. Todd, DVM	Logan County Animal Clinic (Russellville, KY)
Scott S. Tritsch, DVM	Central Kentucky Veterinary Center (Georgetown, KY)
R. Steven Velasco, III, DVM	Kentucky State Veterinarian (statewide), and KBVE Board Member as proxy for the KDA Commissioner of Agriculture (Versailles, KY)
James M. Weber, Jr., DVM	Retired (Alexandria, KY)
Laura E. Williams, DVM	Luna Veterinary Services (Mayfield, KY)
Steven J. Wills, DVM	KBVE Board Member (Owensboro, KY)
Mary A. Zink, DVM	Phoenix Animal Care (Bedford, KY)

III. The following people from the promulgating administrative body responded to the written comments:

Name and Title

John C. Park, DVM, Chairman of the Board
Gene Smith, DVM, Vice Chair of the Board
Dianne J. Dawes-Torres, DVM, Board Member
Thomas M. Dorman, Citizen-at-Large, Board Member
Dale R. Eckert, DVM, Board Member
Tim R. Gardner, DVM, Board Member
Stephanie M. Kennedy, DVM, Board Member
Amy J. Staton, EdD, LVT, Board Member
Steven J. Wills, DVM, Board Member
Michelle M. Shane, Executive Director
Mark R. Brengelman, Attorney and Legal Counsel for the Board

IV. Summary of Comments and Responses

(1) Subject Matter: General comment on entire regulation being applicable to wildlife rehabilitators.

(a) Comment: Dr. Holland, and Mr. Regard – Commentors seek to allow wildlife rehabilitators who are licensed by the Kentucky Department of Fish and Wildlife Resources (KDFWR) to apply for and obtain a certificate for operation as a Kentucky Board of Veterinary Examiners (KBVE)-certified Animal Control Agency (ACA) and to have employees and volunteers under the wildlife rehabilitation permit eligible to obtain a KBVE animal euthanasia specialist certificate in order to perform animal euthanasia on wildlife. They cite 301 KAR 2:075 as justification.

(b) Response: Pursuant to KRS 321.181(50)(b), euthanasia falls under the definition of veterinary medicine. Pursuant to KRS 321.181(7), the definition of an "animal shelter" does not include work with wildlife; the purpose of an "animal shelter" is solely for the control of pet populations. Further, wildlife rehabilitators do not fit the definition of an "animal control agency" as defined in this administrative regulation, which operate under KRS Chapter 258 and for the benefit of a county's obligations to control pet populations.

Pursuant to KRS 321.207, only animals that are owned by a KBVE-certified animal control agency may be euthanized by a KBVE-certified animal euthanasia specialist. As the wildlife held by a KDFWR-certified wildlife rehabilitator is not owned by the rehabilitator, but rather held in temporary custody, any KDFWR-certified wildlife rehabilitator would not qualify for a KBVE certificate for either an ACA or AES.

Pursuant to 301 KAR 4:110, Section 3, KDFWR limits wildlife rehabilitation permit holders to administering drugs under the direction of a Kentucky licensed veterinarian in which a veterinarian-client-patient relationship (VCPR) is established pursuant to KRS 321.185 and 301 KAR 2:075. It is important to note that a VCPR is a patient-specific relationship (except farm work in which a VCPR is herd specific). Under this KDFWR regulation, a veterinarian's direction is required for administration of any drug to wildlife, and the patient specific VCPR must be established in order for the veterinarian to prescribe any drugs. There is no provision by

which a wildlife rehabilitation permit holder is able to make a determination about euthanasia of a captive wildlife patient independent of a veterinarian.

Pursuant to KDFWR regulation 301 KAR 2:075 (updated in February 2023), Section 9(6), only a licensed veterinarian or licensed veterinary technician shall perform euthanasia using AVMA approved non-inhaled chemical methods under KRS Chapter 321. Wildlife rehabilitators under this regulation are specifically prohibited from performing euthanasia on wildlife.

Because multiple statutes and regulations already prohibit wildlife rehabilitators from qualifying as an animal control agency to perform euthanasia, the KBVE declined to make any changes to the proposed amended regulation. KBVE does not seek to promulgate administrative regulations in contravention of its own governing statutes, nor regulations in contravention of another agency's rules. In response to this comment, KBVE declined to make changes to the proposed administrative regulation amendment.

(2) Subject Matter: Definitions required for "dispose", "manage", and "procure" drugs.

(a) Comment: Dr. Velasco – The commentor requested that KBVE add definitions for terms related to the handling of drugs and controlled substances for clarity in the regulation.

(b) Response: KBVE agrees with the commentor as these terms relate to drugs. In response to this comment, KBVE made changes to the proposed amendment to the regulation.

(3) Subject Matter: Section 2 – Designated On-site Manager duty to provide area for euthanasia.

(a) Comment: Ms. Shane – Upon final review of this regulation at the conclusion of the public comment period, the KBVE executive director noticed that Section 2(2) regarding Designated On-site Manager duties failed to list the requirement for a clean and orderly euthanasia area to be accessible for the performance of animal euthanasia. This is something that KBVE Inspectors regularly check for, and should be reflected as a requirement in the regulation.

(b) Response: KBVE determined that Section 2(2) shall be updated to include requirements for a clean and orderly euthanasia area. Following review of this comment, KBVE made changes to the proposed administrative regulation amendment.

(4) Subject Matter: Section 2 – Designated On-site Manager duty to ensure that drugs ordered under a veterinarian's or other DEA registrant holder's DEA Registration are stored separately.

(a) Comment: Ms. Shane – Upon final review of this regulation at the conclusion of the public comment period, the KBVE executive director noticed that Section 2(2) regarding Designated On-site Manager duties failed to list the requirement in KRS 321.207(8) to ensure that drugs ordered under a veterinarian's or other DEA registrant holder's DEA Registration are stored separately.

(b) Response: Pursuant to KRS 321.207(8), KBVE agreed. Following review of this comment, KBVE made changes to the proposed administrative regulation amendment.

(5) Subject Matter: Section 2(3)(a) – Direction that wildlife needs to be redirected to a veterinarian or a Kentucky Department of Fish and Wildlife Resources authorized operator.

(a) Comment: KACCA, Ms. Book, Dr. Grimes, Mr. McNutt – The commentors are concerned that the proposed revisions in the regulation seem to exclude those situations when an animal control officer or animal control agency receive requests from local health departments to euthanize wildlife (e.g., bats, raccoons) for rabies testing. One commentor stated, "There is no mention in regards to euthanasia performed under the local Health Department requests, as well as sick or injured wildlife with human exposure or potential public safety concerns. While this is a regulation under 301 KAR, it is important that Animal Control agencies fully understand the basis of such regulations. In order to remain compliant, it reads as though Animal Controls should have permits in order to respond to sick and/or injured wildlife in order to safeguard citizens and to end suffering in dire circumstances. Suppose local veterinarians would handle such calls; who would be responsible to pick up and transport the animals? Fees for additional permits range from $25 to $250."

(b) Response: After reviewing this comment, KBVE reached out to DEA for clarification on the laws related to transportation of controlled substances without a specific patient purpose. DEA responded in writing, stating, "…be aware that DEA federal regulations rely very heavily on state authority. For example, if the Commonwealth of Kentucky law says that a dog catcher can handle and have access to C-II controlled substances only, then dog catchers would get C-II authority from DEA to only handle that specific drug… Animal Control Officers out in the field are treated much like Vets via the 'Black Bag' Rule. We realize they have different situations out in the wild that would require them to euthanize. As long as they are able to bring those drugs back to the registered location at the end of the day for storage, they are OK."

However, KDFWR recently responded in writing to animal control agencies making a similar comment to their agency, and they stated, "The Kentucky Department of Fish and Wildlife Resources is the regulatory authority for all wildlife in the state. The department regulates methods of take and removal for wildlife species. At this time, there are no exemptions for Animal Control Officers. Currently, the only legal avenue for Animal Control Officers to trap and remove wildlife is with a Nuisance Wildlife Control Operator (NWCO) permit (301 KAR 3:120.). They would need to have a NWCO permit and are subject to the same legal methods of dispatch as NWCOs which do NOT include injectable methods of euthanasia. Wildlife euthanasia via non-inhaled chemical methods can only be performed by a licensed veterinarian or licensed veterinarian technician. In regards to accidental trapping of wildlife. If wildlife are injured in a trap an Animal Control Officer can call a wildlife rehabilitator to arrange for the animal to be picked up, or immediately transport the animal to a permitted wildlife rehabilitator themselves (similar to the general public). If wildlife are not injured they would need to be released on site because transporting and releasing wildlife without a permit is illegal. https://apps.legislature.ky.gov/law/kar/titles/301/002/075/. In regards to public health concerns related to rabies. If wildlife meet the criteria for rabies exposure designated by Public Health they can be dispatched by NWCOs or euthanized by a licensed veterinarian or licensed veterinarian technician. Animal Control does not currently have authority in regulations to euthanize wildlife. If they possess a NWCO permit they could dispatch according to (301 KAR 3:120) which excludes bats. As many bat species in KY are federally listed as endangered or threatened, removal of this species requires special considerations. Public Health should also

contact their KDFWR Regional Biologist, not the local Conservation Officer (Law Enforcement)."

KBVE and KDFWR have a meeting scheduled in December to further discuss this issue and propose appropriate changes that may be needed in statute or regulation.

In response to this comment, and because of the limitations in both KBVE and KDFWR statutes and regulations, KBVE declined to make changes in response to the proposed administrative regulation amendment at this time.

(6) Subject Matter: Approved drugs for use by certified animal euthanasia specialists, specifically sodium pentobarbital with lidocaine.

(a) Comment: AVMA – The commentor states, "We are not able to locate an FDA-approved formulation of sodium pentobarbital with lidocaine at animaldrugs@FDA. Seems like drugs on this list should be FDA-approved. In lieu of this, would this product be compounded from FDA-approved drugs or bulk drug substances (for latter it appears it would need to be on the FDA's approved office stock list)? And, if so, oversight by a veterinarian would be required (compounding is extralabel drug use and ELDU [extra-label drug use] is regulated under federal law). Only a veterinarian can determine that ELDU is needed, and only a veterinarian can prescribe or dispense a medication in an extralabel manner. The veterinarian must direct/supervise ELDU in an animal, including for euthanasia. AVMA would not support a drug being prescribed/dispensed in an extralabel manner by a veterinary technician or euthanasia technician." Further, the commentor states that if KBVE continues to make the drug sodium pentobarbital with lidocaine available for use by certified animal control agencies, then the required Euthanasia by Injection (EBI) curriculum should be updated to include specific education on the limitations of extralabel drugs and the requirement for veterinarian involvement.

(b) Response: The approval for this drug has been carried forward for many years in Kentucky law, but current Members of the Board are uncertain as to its origins. In response to this comment, KBVE removed sodium pentobarbital with lidocaine from the KBVE approved drugs list for certified animal control agency use in the proposed administrative regulation amendment. This change will also prevent the need for a change to the EBI curriculum.

(7) Subject Matter: Section 3(2), (6)(1), etc. – use of the word "approved" as related to drugs approved by the board.

(a) Comment: AVMA – The commentor suggested that the use of the word "approved" in these subsections, specifically, "board-approved" drugs… may be changed to "board-authorized" to avoid any confusion with the FDA drug approval process.

(b) Response: In KRS 321.207, the phrase "The specific drugs approved by the board" appears in reference to the drugs allowable for use by a KBVE-certified animal control agency. However, KBVE appreciated the attempt to provide the highest level of clarity in the proposed administrative regulations. In response to this comment, KBVE changed the word "approved" to "authorized" in the proposed administrative regulation amendment. KBVE has made note to seek an update to the statute to incorporate this change in wording.

(8) Subject Matter: Section 3(3) – "Scheduled drugs (controlled substances) shall be limited to a 30-day supply."

(a) Comment: Dr. Grimes – The commentor is concerned that board inspectors shall understand that drugs are only available in limited quantities (100 to 250 ml single bottles) and that some animal control agencies may not use this amount for many months. They do not want to see an animal control agency get in trouble for having more than a 30-day supply. Additionally, given this supply limit, the commentor asked what should be done in a situation where the animal control agency has to deal with a large animal hording case and many animals may need to be euthanized at the same time.

(b) Response: KBVE is aware that drugs are sold in specific quantities. The purpose of a "30-day supply" is to ensure that animal control agencies do not purchase and maintain more drugs than they can possibly use in 30-days. KBVE conducts annual inspections at all animal control agencies to ensure compliance with KBVE and DEA rules. During the last few years, inspections have revealed that some animal control agencies were stocking up on drugs that were on sale, to the point that the quantities far exceeded anything they might use in many years, and to the point that the drug bottles on the shelves were expired. Given the issues with high turnover and drug diversions in animal control agencies, and the abuse potential of the controlled substances allowed at animal control agencies, KBVE determined it was necessary to put a limit on the quantities allowed for purchase and storage at the certified location. Additionally, it should be noted that in the event of a hording seizure case, the animal control agency may use DEA Form 222 and have additional supply of drugs transferred from another DEA Registrant, either a local veterinarian or another certified animal control agency. In response to this comment, KBVE added clarifying language to the proposed administrative regulation amendment.

(9) Subject Matter: Section 4 – storage requirements for controlled substances should be consistent with DEA requirements.

(a) Comment: AVMA – The commentor is concerned that the storage and record keeping requirements for controlled substances are in alignment with the DEA's requirements for controlled substance storage.

(b) Response: KBVE checked the DEA controlled substances manual for storage requirements in advance of filing. Additionally, because AVMA was concerned with this section, KBVE contacted the DEA registrant help desk in Louisville for confirmation of the requirements. Additional information was received from DEA that the safe or securely locked cabinet should be made of steel, and that the requirement to bolt to the floor is applied only to safes weighing less than 750 lbs. In response to this comment and according to the standards of the DEA, KBVE made changes to the proposed administrative regulation amendment.

(10) Subject Matter: Handling wildlife.

(a) Comment: Dr. Grimes – The commentor asked for clarification on what to do when collecting domestic animals and wildlife is accidentally caught in a trap. What if the wildlife is injured?

(b) Response: The Kentucky Department of Fish and Wildlife Resources rules govern these situations, and not the Kentucky Veterinary Medicine Practice Act. KBVE recommended

that the commentor and others with similar questions reach out to the KDFWR Wildlife Veterinarian Dr. Christine Casey, or to their local KDFWR conservation officer or wildlife biologist. In response to this comment, KBVE declined to make any change to the proposed administrative regulation amendment.

(11) Subject Matter: Definition of acronym "ACA"

(a) Comment: AVMA – Following a review of KBVE's proposed edits in response to comment to the filed administrative regulation, the commentor recommends that the acronym "ACA" be defined at first use in this regulation.

(b) Response: In response to this comment, KBVE changed the proposed administrative regulation amendment to remove this acronym because it was not used anywhere else in the regulation.

(12) Subject Matter: Registration of veterinary facilities.

(a) Comment: Dr. Grimes – The commentor stated that they believed that registration of veterinary facilities was voluntary. They were trying to understand if animal shelters or animal control agencies with a veterinarian on staff would need to register as a veterinary facility. Another situation would be when a mobile veterinarian comes to an animal shelter to conduct a spay/neuter clinic.

(b) Response: As of June 29, 2023, the Kentucky Veterinary Medicine Practice Act requires all locations at which the practice of veterinary medicine occurs to register with the board as a veterinary facility. The KBVE did not intend for certified animal control agencies to need to register as a veterinary facility unless veterinary services are provided to the public at that location, or there is a veterinarian practicing veterinary medicine independent of a mobile unit at that location. The administrative regulations for the governance of veterinary facility registrations are currently under development and early drafts of are now on the KBVE website for advance review and public comment. KBVE intends to file veterinary facility regulations in 2024. In response to this comment, KBVE declined to make any changes to the proposed administrative regulation amendment.

(13) Subject Matter: Opportunity to review proposed changes to the regulations prior to being finalized.

(a) Comment: KVMA, Ms. Hamelback, Dr. Weber – The commentors asked if there would be opportunity for stakeholders to review and provide additional feedback on any proposed changes to the draft prior to final filing with LRC. One commentor asked for a timeline on the final processes for these filed regulations.

(b) Response: Under KRS Chapter 13A, the answer is no. However, KBVE did work on the regulations during two board meetings prior to the public meeting and published the proposed changes to the filed regulations in an effort to allow stakeholder review prior to the final filings. KBVE is required to provide a Statement of Consideration (SOC) to LRC on each

filed administrative regulation that received comments, including a response to all comments received and detailed description of the changes made. Once the final filing is made, the General Assembly Administrative Regulations Review Subcommittee (ARRS) shall have final review. For the current filed regulations, the SOCs were targeted for completion and filing with LRC by October 15; if that date was met, the ARRS would have heard these regulations in November. However, development of the SOCs took longer; the final filing shall occur by November 15 and the ARRS shall hear the regulations in December. After the hearing, Members of the ARRS shall have 90 days to further review the regulations. Unless deferred or found deficient, the filed administrative regulation will go into effect on or before expiration of the 90-day review period. If and when these final filings become effective, the Board may take up the regulation again at any time and file an amendment under the process established in KRS Chapter 13A. Anyone can request that the Board take up the regulation for revision by making the request in writing to the Board's executive director or attending a board meeting and making such a request for review. In response to this comment, KBVE declined to make changes to the proposed administrative regulation amendment.

(14) Subject Matter: Notification procedures on the filing of the administrative regulations were inadequate

(a) Comment: Dr. Todd – The commentor was upset that the KBVE did not send notification to the entire licensee population when these regulations were filed.

(b) Response: KBVE sent notification within one (1) business day to those entities required by law in KRS 13A.270, those on the RegWatch list, and to the Kentucky Veterinary Medical Association (KVMA). Subsequently, KVMA sent an email blast to its Membership. Additionally, the KBVE posted the filings on its website within 24 hours of filing. KBVE notified Dr. Todd how to sign-up for RegWatch notifications, but he had not done so by the time of this SOC filing. KBVE did not send out an email blast to all licensees about these filings because the board did not want to foster confusion amongst the licensee population about when requirements would become effective. Nonetheless, some commentors still interpreted the filings as new rules which they needed to follow immediately, rather than a filing that was still in the public comment phase and not yet effective. In response to this comment, KBVE declined to make changes to the proposed administrative regulation amendment.

(15) Subject Matter: Transcripts of the hearing

(a) Comment: Dr. Beckman, Dr. Bollinger, Dr. Tritsch – Multiple commentors requested copies of a transcript of the hearing.

(b) Response: Pursuant to KRS 13A.270(11), any individual requesting a transcript has the responsibility to pay for the transcript. KBVE did not intend to bring in a court reporter to transcribe the meeting, but did plan to and follow through with capturing an audio recording of the meeting. Prior to the meeting, all parties were notified of this provision in statute and provided the option to arrange for and pay in advance for a court reporter and written transcript. However, all parties declined the written transcript option and instead agreed to accept the audio recording of the public hearing in lieu of a written transcript. Copies of the audio recording were provided to the requestor less than three (3) hours after the conclusion of the meeting. In

response to this comment, KBVE declined to make changes to the proposed administrative regulation amendment.

V. Summary of Statement of Consideration and Action Taken by Promulgating Administrative Body

The public hearing on this administrative regulation was held and written comments were received. The Kentucky Board of Veterinary Examiners responded to the comments and amends the administrative regulation as follows:

Page 1
Section Necessity, Function, and Conformity
Line 10
After "(DEA) to", insert "**procure, manage, and dispose of**"
Delete "order, purchase, manage, and store".

Page 1
Section 1
Line 21
After "Section 1.", insert the following:
"**Definitions.**
(5) "Dispose" in relation to drugs means to destroy or transfer.
(6) "Manage" in relation to drugs means to administer, dispense, or inventory.
(7) "Procure" in relation to drugs means to order, purchase, or receive.
Section 2."

Page 1
Section 1
Line 21
After "Agency.", insert "**A certified animal control agency shall:**"

Page 2
Section 1(1)
Line 1
After "(1)", insert "**Ensure**"
Delete "A certified animal control agency and".

Page 2
Section 1(2)
Line 3
After "(2)", insert "**Identify**"
Delete "A certified animal control agency shall identify".

Page 2
Section 1(3)
Line 6
After "(3)", insert "**Report any**"
Delete "Any"
Delete "shall be reported"

Page 2
Section 1(4)
Line 9
After "(4)", insert the following:
"**Notify the board in writing within ten (10) business days following the termination or severance of employment of a certified animal euthanasia specialist in order that the certificate of the animal euthanasia specialist may be moved to inactive status. (5) Ensure**"
Delete "A certified animal control agency shall ensure".

Page 2
Section 1(5)
Line 12
At the start of the line, insert "**(6)**"
After "(5)", insert "**Submit**"
Delete "(5)".
Delete "A certified animal control agency shall submit"

Page 2
Section 1
Line 13-14
After "Section 5.", insert the following:
"**(7) Report to the board and to DEA within twenty-four (24) hours any suspected diversion of controlled substances or theft of controlled substances. Section 3**"
Delete "Section 2".

Page 3
Section 2(2)(f)
Line 10
After "(f)", insert "**Develop**"
Delete "Shall develop".

Page 3
Section 2(2)(f)

Line 11
Delete "and".

Page 3
Section 2(2)(g)
Line 12
After "(g)", insert the following:
"**Ensure that a designated area is provided for animal euthanasia activities, and that the area is kept clean and orderly, and is maintained as a safe workspace;**
(h) Ensure that drugs ordered under DEA Registration held by any person or entity other than the certified animal control agency are kept in separate secure storage pursuant to KRS 321.207(8); and
(i) Be"
Delete "Shall be".

Page 4
Section 2(3)
Line 5
Delete "or".

Page 4
Section 2(3)
Line 6
After "301 KAR 2:082", insert the following:
";
f. KDFWR wildlife biologist; or
g. KDFWR conservation officer"

Page 4
Section 3
Line 12
At the beginning of the line, insert "**Section 4**"
After Section 3, insert "**Authorized**"
Delete "Section 3".
Delete "Approved"

Page 4
Section 3(1)
Line 14-15
After "only", insert "**sodium pentobarbital**"
Delete "the following board-approved specific drugs".

Page 4
Section 3(1)
Line 17-18
Delete "(a) Sodium pentobarbital; and
(b) Sodium pentobarbital with lidocaine."

Page 4
Section 3(1)
Line 19
After "following", insert "**board-authorized**"
Delete "board-approved".

Page 5
Section 3(3)
Line 4
After "supply", insert "**, or the smallest quantity available for purchase if that quantity is greater than a thirty (30) day supply**"

Page 5
Section 3(4)
Line 6
After "board", insert "**authorized**"
Delete "approved".

Page 5
Section 4
Line 11
At the beginning of the line, insert "**Section 5**"
Delete "Section 4".

Page 5
Section 4(1)
Line 12
After "board", insert "**authorized**"
Delete "approved".

Page 5
Section 4(1)
Line 13
After "in a", insert "**secure steel safe or**"
After "locked", insert "**steel**"

Page 5
Section 4(1)(c)
Line 17
After "(c)", insert "**If the cabinet weighs less than 750 lbs, the**"
Delete "The".

Page 6
Section 5
Line 3
At the beginning of the line, insert "**Section 6**"
Delete "Section 5".

Page 6
Section 6
Line 11
At the beginning of the line, insert "**Section 7**"
Delete "Section 6".

Page 6
Section 6(1)
Line 12-14
After "records of", insert "**procurement, management, and disposal**"
After "administration of", insert "**board authorized**"
After "sedation drugs", insert "**as listed in Section 3 of this administrative regulation**"
Delete "purchases, administration"
Delete "board approved"
Delete ", transfer, and destruction of drugs"

Page 6
Section 6(2)(f)
Line 21
After "of board", insert "**authorized**"
Delete "approved".

Page 7
Section 6(3)
Line 3
After "Records of", insert "**procurement**"
After "of board", insert "**authorized**"
Delete "purchase"
Delete "approved"

Page 7
Section 6(4)
Line 6

After "records of", insert "**procurement, management, and disposal**"
Delete "purchase, destruction, and administration".

Page 7
Section 7
Line 14

At the beginning of the line, insert "**Section 8**"
Delete "Section 7".

Page 8
Section 8
Line 6

At the beginning of the line, insert "**Section 9**"
Delete "Section 8".

Page 8
Section 9
Line 10

At the beginning of the line, insert "**Section 10**"
Delete "Section 9".